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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/079, 703	05/15/98	MAYNARD	R 16436-709

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QM31/0610

 EXAMINER

KLINE, E

ART UNIT	PAPER NUMBER
	3763

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/079,703	Applicant(s) Maynard
	Examiner Eric Kline	Group Art Unit 3763

Responsive to communication(s) filed on May 15, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-73 is/are pending in the application.

Of the above, claim(s) 1-22 and 52-73 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 23-30 and 32-51 is/are rejected.

Claim(s) 31 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5, 6

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, 52-63, shape memory alloy actuators, classified in class 148, subclass 402.
- II. Claims 23-51, drawn to a shape memory alloy medical device, classified in class 604, subclass 95.
- III. Claims 64-73, drawn to a method of forming shape memory actuators, classified in class , subclass .

1. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination claims actuators in a medical device in a lattice and the subcombination claims plural individual actuators. The subcombination has separate utility such as in a hose .

Inventions I and III; and II and III are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as

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claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the actuators could be formed from a shape memory alloy wire instead of a sheet of shape memory alloy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Peter Eng on June 2, 1999 a provisional election was made without traverse to prosecute the invention of II, claims 23-51. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-22, 52-73 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-25, 27-30, 33-36, 38-40, 42-46, 48, 50, 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Takayama et al., U.S. Patent 5,624,380. Takayama et al. discloses a shape

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memory catheter comprising a catheter body formed with a sidewall portion (7a, 7b), a shape memory alloy portion (11a-11e) positioned adjacent the catheter sidewall portion having a lattice network of individually configured shape memory alloy micro-actuators, and an addressable thin-film heater element (90, 91); micro-actuators are arranged in segmented joints (8a); including connecting rings (7a, 7b); includes at least one micro-actuator that expands (Fig 18); wherein that shape memory alloy portion includes at least one addressable heater element to heat a selected combination of at least one micro-actuator for varying the relative stiffness of the shape memory alloy portion and provide relative movement between conduit portions (column 1, lines 50-56); wherein the shape memory alloy portion may be thermally activated to have a different stiffness relative to the catheter sidewall portion (column 1, lines 50-56); wherein the shape memory alloy portion surrounds at least a portion of the catheter body (fig 24); includes a sensor (claim 9); includes a microprocessor unit that selectively activates the micro-actuators (column 6, lines 48-67); wherein the conduit forms at least a portion of a catheter (column 1, line 10); wherein at least one actuator has a substantially rectangular configuration with a buckled surface (Fig 18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 32, 37, 41, 42, 47, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takayama et al. Takayama et al. discloses applicant's invention substantially as claimed. Takayama et al. does not disclose an actuator that contracts upon heating; wherein the shape memory alloy is NiTi; wherein a conduit forms at least a portion of an introducer; wherein the conduit forms at least a portion of a cannula; wherein the actuator is aligned relatively lateral to the scaffolding. It is well known in the art to use NiTi as shape memory alloy for flexible medical devices, therefore it would have been obvious to one of ordinary skill in the art to use NiTi as the shape memory alloy. It would have been obvious to one of ordinary skill in the art to use the invention of Takayama et al. in a various of medical devices such as a introducer and a cannula. It also would have been obvious to one of ordinary skill in the art to align some or all of the actuators in a lateral fashion to perform a bending at a different angle.

Allowable Subject Matter

Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Allowable subject matter is a micro-fabricated transducer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Kline whose telephone number is (703) 305-7350. The examiner can

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normally be reached on Monday-Thursday from 8:00am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Coggins, can be reached on (703) 308-1344. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WYNN WOOD COGGINS
SUPERVISORY PATENT EXAMINER

June 4, 1999

Eric Kline



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